REMARKS

Applicant thanks the Examiner for the very thorough consideration given the present application. Claims 1-2, 5-6 and 8 are currently pending in this application. Claim 1 has been withdrawn from further consideration. No claims have been amended. Accordingly, no new matter has been added.

In view of the remarks herein, as well as the amendments and remarks filed on July 10, 2008, which are incorporated herein in their entirety, Applicant respectfully requests that the Examiner withdraw all outstanding rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 103(a)

Claims 2 and 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshida (U.S. 2003/0232450) (hereinafter Yoshida '450) in view of Takanori et al. (JP 2002-086399) (hereinafter Takanori '399). Applicant respectfully traverses.

The Examiner asserts that Yoshida '450 discloses a method for manufacturing a microfluidic device comprising the steps of: forming a resin layer (2) on a substrate (1), forming a groove or channel (5) by removing a portion of the resin layer by laser processing and forming a "throughhole" or inlet via laser processing. The Examiner acknowledges that Yoshida '450 does not teach or suggest the formation of subsequent resin layers to form a three-dimensional fluidic circuit and relies on the teachings of Takanori '399 to overcome this deficiency.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947

F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be a reason why one of ordinary skill in the art would modify the reference or combine reference teachings to obtain the invention. A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* The Supreme Court of the United States has recently held that the "teaching, suggestion, motivation test" is a valid test for obviousness, albeit one which cannot be too rigidly applied. *Id.* Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.*

The present invention is directed, *inter alia*, to a three-dimensional flow path which is composed of grooves and throughholes and which can mix fluids in a microspace or passage. The present method exhibits unexpected effects during the production of a complex three-dimensional fluid path. According to the present invention, multiple layers in which channels, holes, or the like are formed are stacked to produce three-dimensional passages that are precisely united or connected. Neither Yoshida '450 nor Takanori '399 disclose a fluid path that can mix plural fluids. Moreover, none of the cited references discloses or suggests the presently claimed processing steps which form the specific three-dimensional fluid path of the present invention.

Applicant respectfully submits that the prior art of record fails to teach or remotely suggest a three-dimensional flow path comprising grooves and throughholes, and which can mix fluids in a microspace or passage, as presently claimed.

Yoshida '450 discloses a two-dimensional (planar) fluid flow path. When a plurality of fluids are joined, respective fluids flow in parallel, and sufficient mixing of the fluids is not accomplished. Therefore, mixing must be forced by providing an electrode in the fluidic device, which reduces the cost-effectiveness of the device. Yoshida '450 does not, in any way, teach or suggest a tree-dimensional fluid path. Takanori '399 fails to cure the deficiencies of Yoshida '450.

Takanori '399 discloses three-dimensional fluid paths manufactured by means of a wet process (photolithography). However, Takanori '399 does not teach or suggest the formation of a three-dimensional fluid path according to a dry process that directly utilizes the layers. Moreover, Takanori '399 fails to disclose three-dimensional fluid paths which are capable of three-dimensional fluid mixing, as presently claimed. Additionally, the devices manufactured in accordance with Takanori's "working examples" cannot be used for fluid mixing.

Examples 1 to 3 of Takanori '399 disclose methods to manufacture microdevices (shown in Figs. 1 to 3, respectively) which have one capillary cavity, an inlet and an outlet. Examples 4, 6 and 7 of Takanori '399 disclose microdevices (shown in Figs. 4 and 8), which have passages intersecting three-dimensionally. However, the passages do not communicatively connect to each other. Example 5 of Takanori '399 discloses a microdevice (shown in Figs. 9 and 10) which has a diaphragm valve function. The cut portion 53' and the cut portion 58' are not communicating with each other, because of the intermediate layer 56, which has no cut portion and throughhole. Example 8 of Takanori '399 discloses a microdevice (shown in Figs. 11 to 18) which has a stopper and functions as a pump. The device has two passages (one consisting of cut portions 74 and 74', orifices 77 and 77', horseshoe-shaped cut portions 79 to 79', orifices 82

and 82', and cut portion 84; another consisting of cut portions 88 and 89). These passages are not communicating with each other because of the intermediate layer 85.

Applicant submits that the method of Takanori '399 lacks design freedom, and requires excessive manufacturing time and costs, so as to be unsuitable for practical use in applicable fields. The present method overcomes the problems associated with prior art methods (such as Takanori's). Specifically, the present method has the following advantages:

(i) Reduction of production steps -

The present method significantly reduces the number of steps required. The present method forms grooves and throughholes by a laser ablation method (dry process). Moreover, the present method forms a pattern (groove or throughhole) directly on a resin film, without resorting to a photolithography (wet process).

Takanori '399 forms cut portions (corresponding to grooves and throughholes) by photolithography. In the method of Takanori '399, the following steps are essential: coating of a photosensitive material (wet process), preparation of a photomask (all working examples in Takanori use a photomask), and patterning, exposure and removal of uncured portions, thereby obtaining a semi-cured resin film.

Coating a photosensitive material and preparing a photomask are time-consuming processes. When forming a united three-dimensional device by the method of Takanori, plural photomasks are necessary in order to form patterns which are different from each other. Further, exposure and removal of the uncured portion is also necessary, which requires additional time. Moreover, the semi-cured resin film must be transferred onto another material, so that another curing process needs to be conducted. In the method of Takanori, it is necessary to accurately

stack the resin film onto the lower material, which also takes time. Thus, the method of Takanori is significantly more time-consuming than the present method. In contrast, the present method does not require such stacking accuracy because channels are formed after stacking a sheet of film without any channels. Thus, the present method significantly reduces production steps.

(ii) Accuracy -

The present method can form a three-dimensional flow path (i.e. processing in thickness-direction) with much improved accuracy because a flow path is created by laminating a film and laser-ablating the film.

In order to form a path formed across plural resin films, it is necessary to stack resin films one on top of the other so that the cut portions in the films accurately fit with each other to form a three-dimensional passage. Because μ-TAS is a very small device, the required level of accuracy is extraordinarily high.

Takanori '339 laminates a semi-cured resin film, formed with a cut portion, on another resin film formed with a cut portion. It would be difficult to stack plural resin films so that the cut portions are accurately positioned at the desired locations.

In contrast, the present method laminates an unprocessed resin film on another resin film already formed with, for example, a groove, and thereafter forms, for example, a throughhole in the upper resin film. Thus, the present method can easily connect the groove and the throughhole accurately by controlling the ablation pattern by a computer.

Further, Takanori '399 conducts a curing operation twice: curing is performed to form cut portions and then to bond the resin film onto another resin film. These curing operations can affect the size of the cut portions (see, e.g. Takanori '399, Column 14, lines 42 to 47). In order

to obtain the desired sizes in Takanori '399, it would be necessary to control curing of the resin. However, such an operation would be difficult because curing rates are affected by surrounding conditions.

In contrast, the present method does not require a curing process. Instead, the present method forms a groove and/or throughhole in a resin film after laminating it on another resin film.

Thus, the present method can form a three-dimensional flow path with markedly improved accuracy.

(iii) Design Freedom –

The present method can form a three-dimensional fluid path according to a dry process that directly utilizes the layers. Takanori '399 prepares a fluid path by means of a wet process (photolithography). The present invention can prepare a three-dimensional fluid path that is more complex, due to the specific manufacturing method developed by Applicant.

Since Takanori '399 employs photolithography and transferring of a semi-cured material, it is practically impossible for Takanori '399 to provide a complex three-dimensional fluid path by stacking the films. Thus, one skilled in the art would be required to design a fluid path with certain limitations.

The present method does not require photolithography or transfer steps. Thus, the present method has high freedom of design, and can produce a three-dimensional fluid path with highly reduced costs. The present method is not only suited for mass production, but also for small-scale production of many kind of devices, e.g., production of devices designed for a special use in laboratory research and development.

(iv) Substrate can be re-used –

In the present invention, it is possible to re-use the substrate by washing out the resin films.

Because a micro fluidic device manufactured according to the manufacturing method of the present invention has a fluid flow path provided in a resin film, it is possible to recycle the substrate portion of the device by washing out the portion of the resin film and not throwing away the substrate portion (see page 11, lines 24 to 25 of the present specification). For example, a luminous detection system in genetic diagnosis employs a quartz substrate with remarkably high transparency. It is possible to recycle such expensive substrate with high quality to largely reduce the cost.

Clearly, the cited references, alone or in combination, fail to teach or suggest every limitation of the instant invention. For this reason alone, this rejection should be withdrawn.

Furthermore, assuming *arguendo* that Takanori '399 cured the deficiencies of Yoshida '450, it is noted that references cannot be arbitrarily combined. There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Moreover, according to MPEP 2143.01, the combination of references cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose.

Takanori '399 utilizes photolithography as an essential technology. Thus, it would be impossible to also apply the lamination method of Yoshida '450 when manufacturing a microfluidic device. Therefore, a *prima facie* case of obviousness has not been established.

Accordingly, reconsideration and withdrawal of the present rejection are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

By #42874

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